

K960312

APR 19 1996

## SUMMARY OF SAFETY AND EFFECTIVENESS

### RDI CARDIAC INSULATION PAD

#### I. General Information

- A. Generic Name: Cardiac Insulation Pad
- B. Trade Name of Device: RDI Cardiac Insulation Pad
- C. Applicants Name and Address: RDI  
Richardson, Texas
- D. Pre-market Notification Number: Not assigned

#### II. Indications for Use

The RDI Cardiac Insulation Pad is intended to be used during open heart surgery to insulate the myocardium from the warmer organs and tissues in the body and thus reduce undesired rewarming of the heart.

#### III. Device Description

The RDI Cardiac Insulation Pad consists of a pear shaped, 1/8" thick, closed cell polyethylene foam material. Attached to the foam is a 1/2" wide, 20" long, 4 mil thick, polyvinyl chloride strip referred to as a "tail".

#### IV. Device Classification: Class II

#### V. Safety and Effectiveness:

Substantial Equivalence: This device has been shown to be substantially equivalent to the Sorin/Shiley Inc. Cardiac Insulation Pad #

#### VI. Other Safety and Effectiveness Data:

Materials: Fluid contact materials of construction comply with Tripartite Biocompatibility

Guidance for external devices, blood path direct, short term use.

Sterilization: Validated AAMI/ISO Method 1 validation for Gamma radiation sterilization.

Pyrogenicity: Non-Pyrogenic

Functional Testing:

Thermal Conductivity

Tail Pull Test

Water Absorption

Package Integrity

Shipping & Distribution

Accelerated Aging

Found to be similar to Sorin/Shiley

Found to be similar to Sorin/Shiley

Found to be similar to Sorin/Shiley

Passed in accordance with ASTM  
F1140-88

Passed in accordance with NSTA

Project 1A vibration/drop tests

Successful two year shelf life